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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/053,520	01/17/2002	James E. Rothman	11746/46004	3143
20583	7590	08/23/2006	EXAMINER	
JONES DAY 222 EAST 41ST ST NEW YORK, NY 10017			BASI, NIRMAL SINGH	
			ART UNIT	PAPER NUMBER
			1646	

DATE MAILED: 08/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/053,520	ROTHMAN ET AL.	
	Examiner	Art Unit	
	Nirmal S. Basi	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 19 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18,28,31,33 and 35-99 is/are pending in the application.
- 4a) Of the above claim(s) 28,36-40,42,44,46-47, 49,76,78 and 90-99 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18,31,33,35,41,43,45,48,50-75,77 and 79-89 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>5/19/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Amendments filed 5/19/06 has been entered.
2. Applicant's election with traverse of Group II drawn to a method of inducing an immune response in a subject in need thereof comprising administering to the subject, a composition comprising a conjugate peptide, wherein the conjugate peptide comprises (i) a first portion which binds to a heat shock protein under physiologic conditions, and (ii) a second portion which comprises an antigenic peptide of a pathogen, wherein a heat shock protein is not concurrently administered with the conjugate peptide, whereby an immune response to said second portion is induced in said subject, said immune response being to an antigen of said pathogen, on 5/19/06, is acknowledged. Applicants further elect with traverse from species I, hsp 70; from Species II, geldannmycin; from Species 111, melanoma; from Species IV, a virus; from Species V, mycobacterium; from Species VI, human papilloma virus, and from Species VII, a malarial parasite. However, Applicants submit that the election of Group II renders the elections from Species II and Species III moot. The traversal is on the ground(s) that claims 76 and 78 should be in Group I and not in Group II, and claims 77 and 79-85 should be in Group II and should not be in Group I. Applicant's arguments have been fully considered and are found persuasive. Claims 76 and 78 are removed from Group II and rejoined with Group I and claims 77 and 79-85 removed from Group I and rejoined with Group II. Claims 19-27, 29-30, 32, 34 have been cancelled by Applicant. Claims 28,

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36-40, 42, 44, 46-47, 49, 76, 78, 90-99 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. Claims 18, 31, 35, 41, 43, 45, 48, 50-75, 77, 79-89 are drawn to the elected invention.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 102

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 18, 31, 33, 35, 43, 50-75, 77, 79-89 are rejected under 35

U.S.C. 102(e) as being anticipated by Pramod K. Srivastava (US Patent 5,997,873).

Pramod K. Srivastava discloses (columns 3 and 4), "The purification and isolation of antigenic peptides which are associated (or "chaperoned") by hsp 70 in virus or bacteria-infected or tumor cells. A non-denaturing method may be used to elute chaperoned peptides from the hsp 70-peptide complex described above. In a specific, non-limiting embodiment of the invention, an hsp 70-peptide complex (e.g., as prepared in the example sections which follow, or from the same methods as applied to virus or bacteria-infected cells) may be centrifuged through a CENTRICON 10 filtration assembly in order to remove any low molecular weight material loosely associated with it. The large molecular weight fraction may be recovered and analyzed by SDS-PAGE while the low molecular weight material may be analyzed by HPLC, as described infra.

The hsp 70 preparation in the large molecular weight fraction may be incubated with ATP at a final concentration of about 10 mM at room temperature for 30 minutes and centrifuged through Centricon 10 as before. The two fractions may be recovered, and the ATP treatment of the large molecular weight hsp 70 fraction may be repeated two or more times. The lower molecular weight fractions may then be pooled, concentrated by evaporation in a Speed Vac and then dissolved in 0.1% trifluoroacetic acid (TFA). This material may then be applied to a VYDAC C18 packing material reverse phase HPLC column pre-equilibrated with 0.1% TFA. The bound material may then be eluted at a flow rate of about 0.8 ml/min by a linear gradient of 0 to 79.9% acetonitrile in 0.1% TFA. The ultraviolet light absorbance at 210 nm may be monitored to identify fractions containing antigenic peptide. Antigenic peptides prepared in this manner may be used in immunogenic compositions which may be used to elicit immunity in a mammal in need of such treatment. It may, in certain circumstances, be desirable to administer such peptides linked to or otherwise associated with a carrier molecule, so as to promote immunity.

The present invention also provides for immunogenic compositions which comprise either hsp 70-peptide complex or antigenic peptides. Such compositions may further comprise a suitable carrier such as phosphate-buffered saline (5 mM Na phosphate buffer, 150 mM NaCl, pH 7.1) or other physiologically compatible solution. The immunogenic composition may optionally comprise one or more adjuvants. Suitable adjuvants include, but are not limited to, pluronic tri-block copolymers, muramyl dipeptide and its derivatives, detoxified endotoxin, saponin and its derivatives such as QS-21 saponin derivative and liposomes. “

The antigenic peptides can be prepared from pathogens such as virus and bacteria causing herpes, tuberculosis, meningitis etc. see column 4.

Therefore, Srivastava discloses a method of inducing an immune response using a conjugate peptide (inherently comprise both antigenic peptide that binds heat shock protein and comprises an antigenic peptide of a pathogen) prepared as shown above that may be used in immunogenic compositions which may be used to elicit immunity in a mammal in need of such treatment. Srivastava also discloses that it

may, in certain circumstances, be desirable to administer such peptides linked to or otherwise associated with a carrier molecule, so as to promote immunity. Srivastava meets the limitation of claims 18, 31, 33, 35, 43, 50-75, 77, 79-89 by disclosing a method of inducing an immune response in a subject in need thereof, comprising administering, to the subject, a composition comprising a conjugate peptide (all proteins are considered conjugate peptides because they conjugate amino acid residues), wherein the conjugate peptide comprises (i) a first portion which binds to a heat shock protein under physiologic conditions (domain 1), and (ii) a second portion which comprises an antigenic peptide of a pathogen (domain 2), wherein a heat shock proteins not concurrently administered with the conjugate peptide, whereby an immune response to said second portion is induced in said subject, said immune response being to an antigen of said pathogen. Also, since domains 1 and 2 of Srivastava's conjugate the are linked by amino acids, the conjugate further comprises a peptide linker. Further since the conjugate peptide of Srivastava is isolated from virus or bacteria that bind hsp70 it inherently comprises the first portion peptide of SEQ ID NO:143 and 326. The disclosure of Srivastava meets the limitations of claims 18, 31, 33, 35, 43, 50-75, 77, 79-89 absent evidence to the contrary.

4. Claims 18, 31, 35, 41, 43, 45, 48, 50-75, 77, 79-89 are rejected under 35 U.S.C. 102(e) as being anticipated by Rothman et al (US Patent 6,719,974)

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The applied reference has common inventors (James E Rothman, mark Mayhew, Mee H. Hoe, Alan Houghton) with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Rothman et al (US Patent 6,719,974) discloses a method of inducing an immune response in a subject in need thereof, comprising administering, to the subject, a composition comprising a conjugate peptide, wherein the conjugate peptide comprises (i) a first portion which binds to a heat shock protein under physiologic conditions (comprises the peptide of SEQ ID NO:143 and 326, and (ii) a second portion which comprises an antigenic peptide of a pathogen (various virus and bacteria), (iii) a peptide linker, wherein a heat shock protein is not concurrently administered with the conjugate peptide, whereby an immune response to said second portion is induced in said subject, said immune response being to an antigen of said pathogen (see claims and Detailed Description of the Invention).

The disclosure of Rothman meets the limitations of claims 18, 31, 33, 35, 43, 50-75, 77, 79-89 absent evidence to the contrary.

5. The declaration of Dr. Brian h. Barber has been considered.
6. No claim is allowed.

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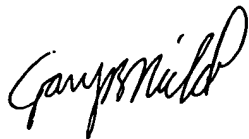
Advisory

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nirmal S. Basi whose telephone number is 571-272-0868. The examiner can normally be reached on 9:00 AM-5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nirmal S. Basi *N*
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8/21/06



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